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COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

Regulatory Certainty Strategy for the Medical Devices Sector

The Federal Commission for Protection from Sanitary Risks (Cofepris) plays a fundamental role in ensuring timely access to safe and quality medical technologies that improve public health, while providing also elements that guarantee investment conditions in Mexico.

The Regulatory Certainty Strategy for the Medical Devices Sector aims to inform the path of the regulation and its harmonization goals in order to strengthen and streamline authorization mechanisms, with international cooperation as a strategic axis.

Therefore, this document seeks to highlight the actions that will enable the achievement of regulatory maturity, optimizing the use of available resources through digitalization, regulatory innovation, and the generation of trust between regulatory authorities and internationally recognized organizations, leveraging their technical expertise and commitment to continuous improvement.

With this work plan, Cofepris aims to offer greater transparency to its processes, avoiding spaces susceptible to corruption. It promises to establish clear normative documents and regulatory criteria, aligned with the best international practices. It explores the implementation of regulatory improvements that reduce

administrative burdens for both, companies and the authority, without implying indiscriminate deregulation, reducing management times, and allowing to redirect efforts to other areas that also require attention.

We can expect agile channels of attention and compliance with international obligations subscribed by our country, as well as clear communication with the industry, academia, other authorities, patients, and all actors involved in the medical devices supply chain. It will comprehensively address the regulatory modernization that this sector deserves.

The global context provides us with a fair opportunity to promote the development of the medical devices sector. In this sense, the Mexican health system aims, through this strategy, to consolidate a better health level and well-being for the population while bring best conditions on for economic development and investments attraction to medical innovation.

I. Objective

Provide regulatory certainty to medical device companies in order to promote productive development and ensure access to technological innovations in medical technology.

II. Strategy

Design a work agenda for 2023-2026 that includes change management, updating the national regulatory framework, and addressing various mechanisms and fora for harmonization.

III. Context

• The medical devices sector has the following characteristics:

i) Diversity of products: ranging from surgical materials to electronic devices for performing computerized axial tomography, or software as a medical device or artificial intelligence.

ii) Research and development: The speed at which academic institutions or companies develop new products.

iii) Adaptability and innovation: The growing technological and digital complexity.

• In this field, Mexico is outstanded for its competitiveness and great production capacity, being recognized in the global market for its manufacturing and assembly processes.

o Currently, our country ranks among the top ten providers of medical devices in the world, as well as being the most important supplier for the United States and the largest exporter in Latin America.

o More than 90% of national production is destined for export, making it an industry that contributes to the integration of supply chains in North America.

o Its sustained growth and the recent boom following the demand for products to address the pandemic caused by the SARS-CoV-2 virus provide further reasons to optimize the regulatory framework to expedite access to medical supplies for patients.

• The COVID-19 pandemic has highlighted more than ever the importance of international cooperation in addressing common health problems, not only to respond to emergencies but also to address situations of backlog related to the limited resources available to regulatory authorities, along with the accelerated pace of new risks to which the population is exposed and the technological advancements developed by the industry.

- Fortunately, the same needs have forced countries to seek convergence of different national regulatory frameworks, achieving fast reconciliation of recognized measures and tools among them.

- Globally, there is coordination of efforts to establish guidelines that facilitate the adaptation of policies ensuring the supply and safety of medical technologies. The International Medical Device Regulators Forum (IMDRF) is the most relevant initiative in this field.

• Population dynamics, health, technology, and trade motivations, therefore, lead to the need for comprehensive strategies to strengthen the sufficiency of all actors in the production chain. Regulatory harmonization and digitalization are the means we have within our scope of competence to optimize access to medical devices.

• This work agenda will enhance the development of this dynamic economic sector, which is strategic for the population health.

- Furthermore, it aims to provide sufficient elements for Mexico to expand its capacity for local innovation by guaranteeing elements of regulatory certainty to strengthen the manufacturing hub and create an environment that fosters investment in clinical research for the development of highly specialized health supplies.

IV. Definition of Regulatory Certainty

- Cofepris defines regulatory certainty as:

  - Fully complying with the regulatory framework for protection against health risks.

  - Providing clarity to users regarding i) authorization requirements and their definition, ii) the internal evaluation process, and iii) the time associated with each assessment stage.

  - Ensuring standardized evaluation based on technical and scientific criteria.

  - Effectively recognizing decisions made by regulatory authorities in other jurisdictions.

  - Guaranteeing the harmonization of technical regulations with internationally recognized standards and references to promote industrial development, access to new medical treatments, and competitiveness.

  - Ensuring the establishment of regulator-regulated interaction instances free from corruption and conflicts of interest through robust and transparent governance processes that facilitate compliance with legal obligations.

  - Implementing regulatory changes with a vision of improvement, harmonization, and regulatory innovation that guarantees a stable regulatory ecosystem with appropriate implementation mechanisms and long-term vision.

  - Transparently disclosing information by publicly providing regulatory foundations and performance data that validate the progress of the regulatory system in compliance with the commitment to continuous improvement.

V. Guiding Principles

• Cofepris' regulatory decisions must contribute to fulfilling the National Development Plan 2019-2024, the Health Sector Program 2020-2024, as well as the General Law on Regulatory Improvement, to provide programmatic consistency and continuity to the changes initiated since the arrival of the President of the Republic, Andrés Manuel López Obrador, such as:

(i) Administrative simplification and regulatory improvement without deregulation to avoid unnecessary bureaucracy and situations prone to corruption;

(ii) Ensuring the supply of health products in the country, and

(iii) The market does not replace the State.

• Its construction will consider: (i) Compliance with international commitments; (ii) Guidelines and recommendations established in forums for harmonizing medical device regulations; (iii) Good Regulatory Practices (GRPs) promoted by the World Health Organization (WHO), the World Trade Organization (WTO), the Organization for Economic Cooperation and Development (OECD), the United States-Mexico-Canada Agreement (USMCA), and other trade agreements that Mexico has signed; (iv) Criteria and requirements for internationally recognized conformity assessment.

• It constitutes Mexico's contribution to the fulfillment of the Health Self-Sufficiency Plan developed by the Economic Commission for Latin America and the Caribbean (ECLAC), based on our country's explicit request during the pro tempore presidency of the Community of Latin American and Caribbean States (CELAC) and presented during the VI Summit of Heads of State held in 2021.

VI. Capacity Strengthening Activities

Medical Device Regulatory Convergence project (MDRC)

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• The Medical Device Regulatory Convergence Project for COVID-19 (MDRC) aims to promote the use of international standards for regulatory purposes of medical devices, expanding the predictability of regulatory ecosystems by aligning them with international norms. To achieve this, the project identifies regulatory convergence through information exchange, training, and resource sharing.

• The project was launched in 2021 with a three-year plan to expand capacity-building efforts, increase the adoption of international standards, save patients' lives, reduce non-tariff barriers, and improve public administration and transparency.

- o It identifies the utilization of international regulatory best practices recommended by the OECD, WTO, and WHO, as well as adherence to IMDRF guidelines and the use of the Medical Device Single Audit Program (MDSAP).

- o Furthermore, it represents a valuable tool to support regulatory convergence. It was promoted to the President of the Republic within the framework of the High-Level Economic Dialogue Mexico-United States (HLED).

• The capacity strengthening activities and the availability of resources and facilities offered by the project are considered timely for better harmonization and implementation of our regulations, not only applicable to the COVID-19 pandemic that initially prompted this phase of execution but also foreseeing

medium- and long-term benefits.

• Within the MDRC implementation, multiple activities have been developed with a focus on building the necessary capacities to address the challenges identified by Cofepris.

- o Currently, we are exploring the utilization of a checklist proposal that facilitates the implementation of Good Regulatory Practices (GRPs) in the process of developing or updating technical standards, in line with national and international commitments. Additionally, the formulation and coordination of training activities are maintained.

World Health Organization (WHO)

• The WHO, as an international specialized agency in health policy management for prevention, promotion, and intervention, is also a reference for guiding our country's health policy, with a commitment to contribute, along with all its Member States, to ensure the right to the highest attainable standard of health for all populations.

- o The WHO has the responsibility to reconcile harmonization and coding systems, propose global health models, coordinate schemes that facilitate access to health products, issue policy recommendations, suggest health and regulatory measures, assist in the development of less privileged countries, aid in the evaluation of the quality, safety, and efficacy of health products, explore strategies for their availability, promote campaigns related to human health, declare public health emergencies, and coordinate international response efforts.

- o As a contributing member of the WHO, specifically in the field of medical devices, Mexico, through Cofepris, has participated in the proposal of the Global Model Regulatory Framework for Medical Devices (GMRF) and therefore takes into consideration its recommendations for national performance.

- o The issue of medical device nomenclature is also discussed within the context of the WHO to seek a common proposal that can be used internationally. However, it is still a matter under discussion, competing with other international proposals such as the Unique Device

Identification (UDI). Since it has not been finalized to date, Cofepris cannot take an institutional stance on the preferred system to be used in Mexico. In this regard, the existing framework is maintained, based on the Global Medical Device Nomenclature (GMDN) system. However, Cofepris will adapt the nomenclature to international references once a concrete proposal and a clear international trend are established.

• In addition to memberships in regulatory harmonization forums, there is another level to assess the performance of a regulatory authority. In order to provide an objective assessment of national regulatory systems, the WHO has developed a methodology and comparative evaluation tool that allows National Regulatory Authorities (NRAs) to assess the effectiveness of their functions regarding a reference for ensuring the quality, safety, and efficacy of regulated products, as well as to identify strengths and areas for improvement and facilitate the formulation of an institutional development plan, prioritizing areas of attention and monitoring progress and achievements.

- o Currently, the WHO has the Global Benchmarking Tool (GBT), originally focused on regulatory agencies for medicines and vaccines, but recently expanded to include the field of medical devices, referred to as GBT+. This tool is designed to evaluate the overall regulatory framework and regulatory functions through a series of sub-indicators that can also be grouped and examined according to categories or cross-cutting themes. To assign a rating, it incorporates the concept of maturity level (adapted from ISO 9004) on a scale from 1 (existence of some elements of the regulatory system) to 4 (operating at an advanced level of performance and continuous improvement).

- o Cofepris considers that once the regulatory updates addressed throughout this strategy are achieved and properly established in operation under the desired new regulatory framework, and when the GBT+ tool has reached the necessary maturity based on the experiences obtained from the current pilot implementations, it will be opportune to undergo the WHO evaluation to demonstrate that its performance is comparable to the level of international best practices.

Pan American Health Organization (PAHO)

• At the regional level, Cofepris participates in the Regional Working Group on Medical Device Regulation, coordinated by PAHO, thus strengthening the regulatory capacities of regulatory authorities through meetings, cooperation initiatives, an adverse event exchange program, alert systems, IMDRF mirror groups, among others.

- o While this initiative encompasses the ideas of the main international harmonization forums, it provides a regional focus through the experience of the participants in its harmonization efforts.

World Trade Organization (WTO)

• For medical devices, as well as for all health-regulated products under the purview of Cofepris, we strive to comply with the rules of the WTO, particularly as provided in the Agreement on Technical Barriers to Trade, which Mexico implements through the Agreement published on December 30, 1994, and in the exercise of best regulatory practices.

VII. Implemented Measures

a) Establishment of the Good Regulatory Practices Committee

• As part of the Regulatory Certainty Strategy for the Medical Device Sector 2023-2026, Cofepris envisions the creation of a Good Regulatory Practices Committee (GRP-C) with the objective of ensuring coherence and feasibility of all changes in the regulatory framework, with a focus on continuous improvement and adherence to GRPs. This collegial body, under the Scientific Committee, has the following responsibilities:

(i) Develop executive work plans for the proper implementation of regulatory modifications that are harmonized, improved, and administratively simplified.

(ii) Oversee and support the implementation of regulations through change management and training actions, both within technical teams and among regulated sectors, to ensure an effective process of adopting the new regulatory framework.

(iii) Generate impact assessment mechanisms before and after changes to the regulatory framework.

• The harmonization and regulatory optimization actions outlined in this document will constitute the work agenda of the GRP-C, ensuring their proper implementation in consensus among different areas of the institution as well as with the public, private, and social sectors.

• To verify such implementation, we have a checklist tool for international and national obligations regarding GRPs , which will allow for recording and ensuring compliance. It will also ensure better use of indicators to adequately measure the performance and progress of regulatory convergence, strengthening the institutional Quality Management System.

VIII. Measures in the Process of Implementation

a) Authorizations of medical devices through recognition of decisions by regulatory authorities from other jurisdictions

• Recognizing regulatory decisions made by reference regulatory authorities (RAs) allows national institutions to optimize response times and allocate resources and capacities to the evaluation of local developments.

• Cofepris has a long history of recognizing authorizations of medical devices issued by other health agencies, such as the United States Food and Drug Administration (U.S. FDA), the Ministry of Health, Labor and Welfare (MHLW) through the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, or Health Canada (HC), through various equivalence agreements.

• However, due to the fast evolution of the regulatory framework, these instruments have become outdated over time, leading to operational difficulties during the evaluation process of new products.

• Therefore, with the purpose of strengthening the execution of Cofepris' attributions, promoting a better use of available resources, and enriching regulatory decision-making, we will restore institutional provisions regarding the use and recognition of information, reports, and decisions issued by other RAs, initiatives, forums, and international organizations.

- o In this regard, Cofepris will establish a guiding policy that serves as a general framework for the application of reliance, thereby strengthening its technical capacity and regulatory functions.

- o Under this directive, areas of opportunity will be identified to optimize specific operational activities and processes, favoring the generation and standardization - to the extent possible - of certain evaluation criteria, reducing management times, increasing confidence levels regarding

harmonization forums and internationally recognized standards, as well as between RAs, and identifying opportunities to redirect efforts towards priority areas.

- o In terms of medical devices, the IMDRF guidelines, including tools such as MDSAP, international standards issued by international standardization organizations, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), recommendations from WHO and PAHO, as well as guidelines derived from international agreements and treaties such as the Mexico, United States, and Canada Agreement (USMCA) or the Pacific Alliance (AP), are the main references for best international regulatory practices considered in this project.
- o This document will be made public in the first half of 2023 and will serve as the roadmap for the future, aiming to be flexible enough to adapt over time.

• Alongside the development of this document, Cofepris will conduct an in-depth assessment of the technical requirements that will be recognized from authorizations issued by other reference RAs, considering marketing authorizations and post-authorization modifications, which will positively impact the comprehensive adjustment of the Equivalence Agreement and the Procedures and Services Agreement.

- o Furthermore, Cofepris will develop user guides to provide clarity on the criteria considered during the evaluation process to obtain a marketing authorization.
- o This update will be completed starting from the fourth quarter of 2023.

• As part of the commitments made by Mexico within the framework of the AP, Cofepris is committed to contributing to the establishment of a mutual mechanism for the recognition of marketing authorizations among the member countries of this trade block.

- o The progress of this commitment depends on the multilateral negotiations reached and the existence of RAs that meet the same criteria for evaluation and health surveillance.

b) Regulatory Harmonization

• To achieve regulatory convergence for medical devices, Cofepris will use documents produced by the IMDRF as a reference for updating the regulatory framework, and the results of MDSAP and ISO 13485 will be considered for Good Manufacturing Practice acreditation. To strengthen this process, Cofepris will actively and continuously participate in the working groups and biannual sessions of the IMDRF to achieve Observer Membership, in compliance with the requirements established by the forum. In the same vein, Cofepris aims to achieve Affiliate Membership of MDSAP in 2023, once the requirements for such membership have been met. To accomplish this, Cofepris commits to referencing international regulatory trends synthesized by this forum in the local regulatory framework.

- o In this forum, we will collaborate on the development of guidance documents to address common regulatory challenges in public health arising from the globalization of production and supply chains of medical devices and emerging technologies, and to promote innovation through clear and practical regulatory expectations.

  - As a regulatory authority, we will demonstrate long-term active participation and continuous progress in its implementation at the national level.

- o With the aim of achieving this objective, in 2021, Cofepris officially modified the Official Mexican Standard (NOM) 241-SSA1-2021, Good Manufacturing Practices for Medical Devices.

  - This update incorporated the provisions of ISO 13485 regarding the Quality Management Systems of medical device manufacturers into national regulations, which came into effect by the end of the second quarter of the year.

  - After a reasonable period of evaluation for usefulness and compliance, Cofepris will propose further modifications to address identified areas for improvement, in addition to the improvements identified thus far. This update proposal will be included, in accordance with Good Regulatory Practices, in the National Quality Infrastructure Program, with the aim of officializing it in early 2025.

- In line with the above, between the first and fourth quarters of 2023, Cofepris will update the Official Mexican Standards NOM-137-SSA1-2008 “Labeling of Medical Devices” and NOM-240-SSA1-2012 “Installation and Operation of Technovigilance,” in accordance with Good Regulatory Practices.

• Recognition of MDSAP is included among the binding commitments of the Medical Devices Sectoral Annex of the USMCA. Therefore, Cofepris, with the purpose of contributing to its strengthening, seeks to obtain membership in MDSAP. We meet the application requirements, and we also have support from the FDA and the United States Standards Alliance to facilitate its implementation, providing support for capacity strengthening and monitoring the accession process.

c) Reclassification of Medical Devices

• Mexico has a classification of medical devices divided into three categories:

- Class I: Devices with minimal risk to the human body. Their safety and effectiveness are fully evaluated, and they are generally devices that are not introduced into the human body.

- Class II: Products that may have variations in their composition or concentration. They are introduced into the human body for a period of less than 30 days.

- Class III: New or recently accepted products in medical practice, or products introduced into the human body and remaining for more than thirty days.

• Although this classification has allowed for a proper risk-based evaluation of these health products, it is currently outdated compared to some international provisions, which complicates regulatory harmonization or the understanding of regulatory provisions for newly established companies in the country.

• Therefore, Cofepris, through the Pharmacopeia of the United Mexican States, will issue the necessary provisions to achieve a harmonized classification with international recommendations, migrating to a classification into four

categories: i) Low risk, ii) Low to moderate risk, iii) Moderate to high risk, and iv) High risk.

• This classification will allow: i) Adequate evaluation times for each type of product, ii) Risk-based criteria and requirements, and iii) The lowest-risk category to function as a notification to the health agency, as these products do not require evaluation due to the low probability of causing harm to health.

• Cofepris projects that the new classification will be officialized in the second quarter of 2023, while the relevant administrative modifications will be available in the second half of the year.

d) Digitization as a Means of Optimization

• As a general strategy for regulatory optimization, digitization avoids spaces susceptible to corruption, complies with established legal timelines, and addresses backlog. In this regard, the health authority is addressing the issue through two approaches:

(i) Self-managed procedures: Creation of procedures with automatic responses

(ii) Remote evaluation through virtual means: Exploring the expansion of scopes, with a direct impact on reducing processing times.

• In 2022, Cofepris released the first functionalities of the digital platform, including the electronic evaluation of the first extension of medical devices and the issuance of automatic resolutions for subsequent extensions.

o Additionally, throughout 2022, Cofepris enabled self-managed digital procedures (such as operating notifications, responsible party notifications, and advertising notifications). Thanks to this modality, the agency can efficiently resolve some processes electronically.

• The next functionality in the digitization process is the release of the platform for Modifications to the Authorization Conditions of Medical Devices, scheduled for the first quarter of 2024.

o The platform will offer two types of procedures: i) Administrative modifications, which will have notifications of automatic resolutions, and ii) Technical modifications.